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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,114	06/16/2000	Trudy H. Grossman	HMR2050	2671

7590

11/23/2001

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EXAMINER

LOEB, BRONWEN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 11/23/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/596,114		GROSSMAN ET AL.	
	Examiner		Art Unit	
	Bronwen M. Loeb		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 28-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 28-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment filed 10 September 2001 in which claims 19-27 were cancelled, claims 1, 9, 11, 14 and 16 were amended and new claims 28-29 were presented.

Any rejection from any previous action not repeated herein has been withdrawn.

Claims 1-18 and 28-49 are pending.

Response to Amendment

Claims 13, 15 and 18, and newly added claims 44, 46 and 49, stand rejected under 35 U.S.C. §112, first paragraph for reasons of record and as discussed below.

Claims 1-12 and 14, and newly added claims 28-43 and 45, stand rejected under 35 U.S.C. §102(b) as being anticipated by Berg et al paragraph for reasons of record and as discussed below.

Claims 1-7, 9, 10 and 14, and newly added claims 28-36, 38, 40, 41 and 45, stand rejected under 35 U.S.C. §102(e) as being anticipated by Reznikoff et al paragraph for reasons of record and as discussed below.

Claims 1, 2, 5-7, 14, 16 and 17, and new claims 28, 29, 32-36, 38, 45, 47 and 48, stand rejected under 35 U.S.C. §102(b) as being anticipated by Marsch-Moreno et al paragraph for reasons of record and as discussed below.

The objection to the Drawings is maintained for reasons of record as Applicant did not address this objection in the amendment filed 10 September 2001.\

New rejections and objections are presented below.

Response to Arguments

Claim Rejections - 35 USC § 112

1. Claims 13, 15 and 18 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is extended to new claims 44, 46 and 49.

Claims 13 and 44 are drawn to a specific vector, pTRANS-SacB. Claims 15 and 46 are drawn to a specific vector, pTRANS. Claims 18 and 49 are drawn to a specific vector, pBacTA.PUC2. Because it is not clear that the identical vectors are freely available or can be reproducibly isolated from nature a biological deposit for patenting purposes is required.

Applicant's arguments filed 10 September 2001 have been fully considered but they are not persuasive. Applicant argues that the materials to produce these vectors are commercially available and that the specification provides teachings that enable one of skill in the art to manufacture these vectors using routine laboratory techniques. These arguments are not persuasive because one of skill in the art cannot exactly reproduce the claimed vector. A specific plasmid is not merely a collection of elements, but rather a collection of elements arranged in a distinct fashion with regard to sequence and the spacing of elements. Although the starting material may be commercially available, the specification fails to provide the detailed specifics to enable

one of skill in the art to generate the claimed plasmids. Applicant cites p. 1, lines 15-28 as exemplifying the teachings of the specification. In this example, there is no specific teaching as to exactly where in the sequence of pGPS1 the moderate copy origin of replication is inserted, nor teachings about the specific sequence of the universal primer sites and exactly where in the sequence of pGPS1 they are located, nor exactly where the sacB gene was inserted. The specification similarly fails to teach the specifics about the construction of the other two claimed plasmids in such a way as to enable one of skill in the art to reproduce exactly either plasmid. The rejection is therefore maintained.

Claim Rejections - 35 USC § 102

2. Claims 1-12 and 14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Berg et al (USP 5,645,991). Applicant's arguments filed 10 September 2001 have been fully considered but they are not persuasive. Applicant argues that significant differences exist between the teachings of the Berg et al and the instant invention and recite a number of these differences which include the number of contraselectable marker genes, the origin of replication and the location of the transposon in the claimed vector. While these differences may exist in the teachings in the specification, the open claim language of the pending claims does not exclude the plasmids taught by Berg et al. Therefore the claims read on the plasmids taught by Berg et al and are anticipated.
3. Claims 1-7, 9, 10 and 14 stand rejected under 35 U.S.C. §102(e) as being anticipated by Reznikoff et al (USP 5,948,622). Applicant's arguments filed 10

September 2001 have been fully considered but they are not persuasive. Applicant argues that the vector taught by Reznikoff et al has three selectable markers and that their claims do not recite three counterselectable markers. While it is true that the pending claims do not specifically recite three counterselectable markers, the open language of the pending claims encompass such a possibility. Furthermore, Reznikoff et al teach at least one selectable marker (col. 11, line 12-13) and thus are not restricted to the three markers illustrated in Figure 1. Therefore, the claims are anticipated by Reznikoff et al.

4. Claims 1, 2, 5-7, 14, 16 and 17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Marsch-Moreno et al (1998 Plasmid 39: 205-214). Applicant's arguments filed 10 September 2001 have been fully considered but they are not persuasive. Applicant argues that their claims differ from the vectors taught by Marsch-Moreno et al because Marsch-Moreno et al teach that the transposase gene is outside the borders of the transposon and is defective due to that location, and also because a mutated transposase gene having increased transposition activity is taught. While the pending claims do not recite a transposase gene, neither do they exclude a mutated transposase gene. The open claim language therefore encompasses the teachings of Marsch-Moreno et al and are anticipated by the teachings.

New Grounds of Rejections

5. Applicant is advised that should claims 1-18 be found allowable, claims 28-49 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). See 35 U.S.C. §102 rejections below regarding interpretation of “consisting essentially of” in claims 28-49.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. New claims 28-42 and 45 recite the transistional phrase “consisting essentially of”. Absent a clear indication in the specification of what the basic and novel characteristics are, this phrase has been construed as equivalent to “comprising”. See MPEP §2111.03.

8. Claims 28-43 and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Berg et al (USP 5,645,991). Berg et al anticipates these claims for the same reasons as presented for claims 1-12 and 14 in the Action of 9 May 2001 and as further discussed above.

9. Claims 28-36, 38, 40, 41 and 45 are rejected under 35 U.S.C. §102(e) as being anticipated by Reznikoff et al (USP 5,948,622). Reznikoff et al anticipates these claims for the same reasons as presented for claims 1-7, 9, 10 and 14 in the Action of 9 May 2001 and as further discussed above.

10. Claims 28, 29, 32-36, 38, 45, 47 and 48 are rejected under 35 U.S.C. §102(b) as being anticipated by Marsch-Moreno et al (1998 Plasmid 39: 205-214). Marsch-Moreno et al anticipates these claims for the same reasons as presented for claims 1, 2, 5-7, 14, 16 and 17 in the Action of 9 May 2001 and as further discussed above.

Conclusion

Claims 1-18 and 28-49 are rejected. Claims 13, 15, 18, 44, 46 and 49 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

November 17, 2001



REMY YUCEL, PH.D
PRIMARY EXAMINER